

### **REMARKS**

Claims 97-98, 105-106, and 119-120 have been examined. Claims 98, 106, and 120 are canceled herein. The right to prosecute the subject matter of the canceled claims in a subsequent continuation, continuation-in-part, or divisional application is hereby expressly reserved. Claims 97, 105, and 119 have been amended. Claims 129-140 are new.

The amendments to claims 97, 105, and 119 are supported by the original claim language and the specification as originally filed, including non-limiting exemplary support at, e.g., page 6, lines 5-8; page 9, line 9 to page 10, line 3; page 14, line 16 to page 15, line 6. New claims 129-140 are supported by the original claim language and the specification as originally filed, including non-limiting exemplary support at, e.g., page 5, lines 6-15; page 6, lines 1-8 and 23-25; page 7, line 30 to page 8, line 3; and page 16, lines 1-6 and 23-25. No new matter is introduced by this Amendment, nor does this amendment necessitate a new search. Entry of this response is respectfully requested.

Upon entry of this amendment, claims 97, 105, 119 and 129-140 are pending.  
Reconsideration is respectfully requested in light of the following remarks.

### **Claims Rejections – 35 USC §§ 102/103**

Claims 97, 98, 119 and 120 are rejected under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Buechler (U.S. Patent No. 5,458,852 (the '852 patent)). Claims 98 and 120 have been cancelled, rendering rejection of these claims moot. Applicants respectfully traverse the rejection of the remaining claims.

Amended claims 97 and 119 are not anticipated by Buechler because Buechler does not disclose each and every limitation of the claimed invention. In order for Applicant's claims to lack novelty under 35 U.S.C. § 102 (*i.e.*, be anticipated), each and every element of the claimed invention must be disclosed in a single prior art reference. *Akzo N.V. v. U.S. International Trade Comm'n*, 808 F.2d 1471 (Fed. Cir. 1986), cert. denied, 482 U.S. 909 (1987); *see also Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1986); *In re Paulson*, 30 F.3d 1475 (Fed. Cir. 1994); *Rowe v. Dror*, 112 F.3d 473 (Fed. Cir. 1997). The Examiner has failed to provide a sufficient showing that the independent claims are anticipated, at least for the following reasons.

Amongst other limitations, claims 97 and 119, as amended, recite “a label is provided in said reaction chamber” (or, in claim 119 “a detectable label are added to said reaction chamber”); “a signal processor for determining said progress and time of completion of said assay...selected from the group consisting of a rate of change of the amount of said signal and an absolute amount of said signal”; and “wherein the label does not appreciably bind to assay reagents in said assay device.

The Examiner asserts that the ‘852 patent allegedly discloses a device comprising a reaction chamber, a time gate for measuring the reaction in a given period of time, and an optical system. In addition, the Examiner asserts that the ‘852 patent allegedly discloses that the label “does not appreciably bind to any reagent in said assay device.” However upon examination of the cited disclosure, it is evident that there is no disclosure of a label that does not appreciably bind to assay reagent, nor is there disclosure of the detection of such a label, as is required in independent claims 97 and 119. The label disclosed in the context of a “Signal Development Element” creates a detectable signal “as a result of the assay process.” See ‘852 at column 3, lines 17-36 (Emphasis added). Indeed, the Office Action acknowledges that the signal-producing reagent of Buechler is the “same signal-producing reagent that binds to the positive control”; a component of an assay reagent. Office Action at page 6.

Furthermore, the ‘852 patent does not disclose a signal processor for determining progress and time of completion of the assay by either a rate of change of the signal or the absolute amount of signal generated from a label that does not bind to an assay reagent. The only aspect of rate disclosed by Buechler requires the binding of an entity from the reaction mixture, which is an assay component. See Buechler at column 8 lines 4-10. Thus, Buechler ‘852 does not anticipate independent claims 97 and 119.

The Office Action also states that “one of ordinary skill in the art would have been motivated to measure the label reagents in the ‘time gate’ in order to detect the reagents throughout the assay device...” as supporting that Buechler’s positive control would be analogous to the independent control described in the present specification. Office Action at pages 5-6. However, because Buechler discloses that the positive control is related to the signal development element, which is defined as “a visually or instrumentally detectable signal as a result of the assay process” (Buechler at Column 3, lines 17-19) there is no teaching or

suggestion that would motivate one of skill in the art to: 1) substitute a label that does not bind assay reagents; and 2) devise a means to monitor the rate or absolute generation of the signal of such a label that is distinct from the signal generated from the assay. Buechler '852 teaches away from the apparatus of the instant claims because Buechler requires that the positive control signal result from the assay process rather than being independent from it. Furthermore, Buechler does not teach or suggest the limitation "a signal processor for determining said progress and time of completion of said assay...selected from the group consisting of a rate of change of the amount of said signal and an absolute amount of said signal."

Because Buechler does not disclose, either expressly or inherently, every limitation of the claims, Buechler does not anticipate the invention of claims 97 and 119. In the alternative, Buechler does not teach or suggest aspects that would, to the person of ordinary skill in the art, render the claims obvious.

Applicants respectfully request that the rejection be withdrawn.

#### **Claims Rejections – 35 USC § 103(a)**

Claims 105 and 106 are rejected under 35 USC 103(a) as being unpatentable over Buechler (US Patent #5,458,852) in view of Foster et al. (US Patent #4,444,879). Claim 106 has been cancelled, rendering rejection of this claim moot. Applicants respectfully traverse the rejection of claim 105.

The amended claims are not obvious over the combination of references cited by the Examiner because the combination of references does not teach or suggest the invention as claimed.

The Examiner acknowledges, at page 8, that Buechler does not teach the assay as a kit, and cites Foster to cure the deficiencies of Buechler.

As discussed above (but similarly applicable to claim 105), Buechler does not disclose or suggest the claim limitations of "a label is provided in said reaction chamber"; "a signal processor for determining said progress and time of completion of said assay...selected from the group consisting of a rate of change of the amount of said signal and an absolute amount of said signal"; and "wherein the label does not appreciably bind to any assay reagents in said assay device." Similarly, Foster does not teach or suggest these claim limitations.

All references to label in Foster are in the context of reagents that bind to assay components. Thus, Foster teaches away from the limitation of a label that does not appreciably bind assay reagents.

Further, Foster does not teach or suggest the limitation of a signal processor for determining progress and time of completion of the assay. Indeed, Foster teaches away from the monitoring of the reaction by disclosing that the complex is generally completely formed “within from about 0.5 to about 5 hours.” Foster at column 9, lines 40-41. It is contended that such a broad range could not serve as the basis for a suggestion to one of skill in the art to monitor and determine the progress and time of completion of the assay.

Lastly, Foster does not teach or suggest the limitation of determining rate of change of the amount of said signal. Foster discloses that the kit makes a single determination by the addition of enzyme substrate and incubation for one hour before determination of an optical density; precluding a determination of rate of change. Foster at column 15, lines 47-51.

Thus, for the reasons described above, the combined prior art does not teach or make obvious the claimed invention. It is therefore respectfully requested that the rejection of claim 105 under 35 U.S.C. § 103(a) be withdrawn.

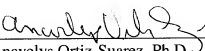
### CONCLUSION

Applicants respectfully submit that all rejections have been obviated and that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. If any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the telephone number listed below so that they may be resolved without the need for an additional action.

The third month extension fee for a large entity is provided along with this Response. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application or credit any overpayment to Deposit Account No. 23-2415 (Docket No. 36671-740.301).

Respectfully submitted,

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